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PATENT
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Assistant Commissioner for Patents
Washington, D.C. 20231

On June 11, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: _____
Reg # 38,515

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Charanjit R. Behl, et al.

Application No.: Unassigned

Filed: June 11, 2001

For: NASAL DELIVERY OF APOMORPHINE IN COMBINATION WITH GLYCOL DERIVATIVES

Art Unit: Unassigned

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

IN THE SPECIFICATION:

Please replace the paragraph following the heading "CROSS REFERENCE TO RELATED APPLICATIONS" on page 1 with the following new related applications reference information. --This application is a Continuation of Application Serial No. 09/665,500, filed September 19, 2000, which is a Continuation-in-part of co-pending U.S. Application Serial No. 09/334,304, filed June 16, 1999.--

IN THE CLAIMS:

Please cancel claims 1-20, without prejudice.

Please add new claims 21-40, as follows.

--21. A nasally administered pharmaceutical formulation for treating sexual dysfunction in a mammalian subject comprising a therapeutically effective amount of a dopamine receptor agonist in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said dopamine receptor agonist to produce a therapeutic result in said subject within about 30 minutes or less.

22. The nasally administered pharmaceutical composition of Claim 21, wherein administration of said dopamine receptor agonist in said formulation for enhanced nasal delivery yields enhanced nasal absorption of said dopamine receptor agonist to produce a therapeutic result in said subject within about 15 minutes or less.

23. A nasally administered pharmaceutical formulation for treating sexual dysfunction in a mammalian subject comprising a therapeutically effective amount of a dopamine receptor agonist in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said dopamine receptor agonist resulting in a time to maximal plasma concentration (tmax) of said dopamine receptor agonist in said subject of about 20 minutes or less.

24. The nasally administered pharmaceutical composition of Claim 23, wherein administration of said dopamine receptor agonist in said formulation for enhanced nasal delivery yields enhanced nasal absorption resulting in a time to maximal plasma concentration (tmax) of said dopamine receptor agonist in said subject of about 15 minutes or less.

25. The nasally administered pharmaceutical composition of Claim 21, wherein said subject is a female.

26. The nasally administered pharmaceutical composition of Claim 23, wherein said subject is a female.

27. The nasally administered pharmaceutical composition of Claim 21, wherein said therapeutic response is selected from an improvement of sexual desire in a male or female subject, or amelioration of erectile dysfunction affecting an erectile tissue of a male or female subject.

28. The nasally administered pharmaceutical composition of Claim 23, wherein said sexual dysfunction is selected from reduced sexual desire in a male or female subject, or erectile dysfunction affecting an erectile tissue of a male or female subject..

29. The nasally administered pharmaceutical composition of Claim 21, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

30. The nasally administered pharmaceutical composition of Claim 23, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

31. The nasally administered pharmaceutical composition of Claim 21, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

32. The nasally administered pharmaceutical composition of Claim 23, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

33. A method of increasing sexual desire or eliciting an erectile response in a male or female mammalian subject comprising nasally administering a therapeutically effective amount of a dopamine receptor agonist in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said dopamine receptor agonist to produce a therapeutic result in said subject within about 30 minutes or less.

34. The method of Claim 33, wherein administration of said dopamine receptor agonist in said formulation for enhanced nasal delivery yields enhanced nasal absorption of said dopamine receptor agonist to produce a therapeutic result in said subject within about 15 minutes or less.

35. A method of increasing sexual desire or eliciting an erectile response in a male or female mammalian subject comprising nasally administering a therapeutically effective amount of a dopamine receptor agonist in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said dopamine receptor agonist resulting in a time to maximal

plasma concentration (tmax) of said dopamine receptor agonist in said subject of about 20 minutes or less.

36. The method of claim 35, wherein administration of said dopamine receptor agonist in said formulation for enhanced nasal delivery yields enhanced nasal absorption resulting in a time to maximal plasma concentration (tmax) of said dopamine receptor agonist in said subject of about 15 minutes or less.

37. The method of Claim 33, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

38. The method of Claim 35, wherein said dopamine receptor agonist is selected from the group consisting of apomorphine, chemically modified equivalents and pharmaceutical salts thereof.

39. A nasally administered pharmaceutical formulation for treating difficulty in achieving or inability of achieving orgasm in a female mammalian subject comprising a therapeutically effective amount of a dopamine receptor agonist in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said dopamine receptor agonist resulting in a time to maximal plasma concentration (tmax) of said dopamine receptor agonist in said subject of about 20 minutes or less.

40. A method of reducing difficulty in achieving or inability of achieving orgasm in a female mammalian subject comprising nasally administering a therapeutically effective amount of a dopamine receptor agonist in a formulation for enhanced nasal delivery which yields enhanced nasal absorption of said dopamine receptor agonist resulting in a time to maximal plasma concentration (tmax) of said dopamine receptor agonist in said subject of about 20 minutes or less, before, during or after sexual activity.--

REMARKS

Claims 21-40 are pending in the application. By this Preliminary Amendment, claims 1-20 have been canceled, without prejudice, and new claims 21-40 have been added to more distinctly claim certain aspects of the invention. All the claims added herein are fully supported by the specification, and no new matter has been added to the application. Entry of this Preliminary Amendment is respectfully requested.

CONCLUSION

Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Jeffrey J. King
Reg. No. 38,515

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JJK:waw
SE 5008684 v1